UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,	:	**No.05 CV 5393**
REDACTED	:	**AMENDED COMPLAINT**
FAIR LABORATORY PRACTICES ASSOCIATES,	:	**JURY TRIAL DEMANDED**
Plaintiffs,	:	
v.	:	
QUEST DIAGNOSTICS, INCORPORATED,	:	
Defendant.	:	

AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. § 3279 *ET SEQ.*];

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Pursuant to the aforementioned statutes and codes, the United States of America,

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ex rel Fair Laboratory Practices Associates,

(collectively the "Plaintiff" or "Relator"), by and through their undersigned attorneys, for their Amended Complaint, allege as follows:

I. NATURE OF ACTION

1. The Amended Complaint, to be filed under the pre-existing seal, asserts claims under the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729-33, ("FCA" or "False Claims Act"), based upon violations of the Federal health care anti-kickback statute, 42 U.S.C. § 1320a-7b(b)("Anti-Kickback Statute" or the "Federal Anti-Kickback Statute"), the Stark Amendments to the Medicare Act, 42 U.S. § 1395nn ("Stark Law" or "Federal Stark Law"), and other related provisions, REDACTED being false claims and statements submitted to the United States resulting in actual damages in excess of $1 billion during the record from 1996 to date, without regard to fines or penalties. All charges brought herein against the Defendant are based upon Defendant's false claims and statements made in connection with the submission of Medicare and/or Medicaid reimbursement forms from at least January 1, 1996 and continuing to the present.

2. The false claims herein alleged are based, *inter alia*, on express or implied certifications by Defendant that it complied with applicable Federal law REDACTED including the Federal Anti-Kickback Statute and the Stark Law. In fact, the "pull through"

scheme used by Defendant for more than a decade, wherein Defendant charged managed care organizations below-cost rates for tests under capitated programs in exchange for the referral of Medicare and Medicaid tests by the organizations' physicians, violated both the Federal Anti-Kickback Statute and the Stark Law, REDACTED

Violations of these laws give rise to causes of action under the False Claims Act

REDACTED

3. (a) Section 1320a-7b(b)(2) of the Anti-Kickback Statute prohibits any person or entity from offering or paying any "remuneration" to induce such person to purchase or order any service or item for which payment may be made under a Federally funded health care program. Under the Anti-Kickback Statute, a clinical laboratory company may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians to order laboratory tests that are reimbursed under Medicare or Medicaid as here alleged.

(b) Section 1320a-7b(b)(2) of the Anti-Kickback Statute also prohibits any person or entity from offering or paying any remuneration to induce such person "to arrange for or recommend" purchasing or ordering any service or item for which payment is made under a Federally funded health care program. Under the Anti-Kickback Statute, a clinical laboratory company may not offer or pay any remuneration, directly or indirectly, to induce a person, including a health maintenance organization, to arrange for or recommend to its physicians the purchasing or ordering of any service or item, including a laboratory test, that is reimbursed under Medicare or Medicaid as here alleged. Significantly, Section 1320a-7b(b)(2) does not contain any requirement that remuneration be paid to the person ordering the item or service for which Federal reimbursement is sought.

4. (a) Section 1395nn(a)(1) of the Stark Law prohibits a clinical laboratory from presenting or causing to be presented, Medicare claims for payment for designated health services furnished pursuant to patient referrals from physicians having a prohibited "financial relationship" with the clinical laboratory. The Stark Law establishes a clear rule that Medicare will not reimburse a clinical laboratory for items or services ordered by physicians who have an improper financial relationship, directly or indirectly, with a clinical laboratory, regardless of the intention of the parties, as here alleged.

(b) "Financial relationship" is defined in the regulations implementing the Stark Law as including a "compensation arrangement," which, in turn, is defined as "any arrangement involving remuneration . . . between a physician . . . and a [laboratory]." Remuneration is defined to include "any payment or other benefit made directly or indirectly "in cash or in kind." 42 CFR §411.351. Remuneration, under the Stark Law, is the same as remuneration under the Anti-Kickback Statute.

(c) The so-called Phase III Regulations under the Stark Law distinguish a "direct compensation arrangement," that is, one where "remuneration passes between the referring physician . . . and [a clinical laboratory] without intervening persons or entities" (§411.354 (c)(1)(i)) from an "indirect compensation arrangement." A direct compensation arrangement would exist, for example, when Quest contracted with a physician group or network of physicians, such as an independent practice association or a preferred provider organization.

(d) An "indirect compensation arrangement" exists under the Phase III Regulations (§411.354 (c)(2)) if (i) "[b]etween the referring physician . . . and [the clinical laboratory] there exists an unbroken chain of any number . . . of persons or entities that have

financial relationships between them (that is, each link in the chain has . . . a compensation arrangement with the preceding link)," (ii) "[t]he referring physician . . . receives . . . compensation . . . that varies with . . . the volume or value of referrals or other business generated by the referring physician to [the clinical laboratory]" and (iii) the laboratory "has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician . . . receives [such remuneration or compensation]." An indirect compensation arrangement would exist, for example, when Quest contracted with a health maintenance organization which, in turn, contracted with a physician group or network of physicians.

5. In its attempts to deceive Medicare and Medicaid, the Defendant prepared, caused to be prepared, reviewed, submitted and/or approved false reimbursable costs of as much as hundreds of million dollars annually, and received reimbursements to which it was not entitled. Damages will continue to be incurred until the charges herein are resolved.

II. JURISDICTION AND VENUE

6. This Court has jurisdiction over this action pursuant to 31 U.S.C. § 3729, 3732(b), et seq. and 28 U.S.C. § 1331 and 1345,

REDACTED

7. Venue is appropriate pursuant to 31 U.S.C. § 3732, 3732(b) and 28 U.S.C. § 1391(b) and (c) in that certain of the claims herein arose, and certain of the acts of Defendant which are the subject of this action occurred, within this District. In addition, Defendant resides in and/or transacts business in this District.

III. FALSE CLAIMS ACT

8. The False Claims Act was originally enacted during the Civil War, and was substantially amended in 1986. Congress amended the Act to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the FCA, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

9. The FCA provides that any "person," including a corporation such as the Defendant, who knowingly or recklessly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

10. The FCA allows any person having information about a false or fraudulent claim against the Government to bring an action for himself (or itself), and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

IV. THE PARTIES

11. Relator (also, "Plaintiff") is Fair Laboratory Practices Associates, a Delaware general partnership, which, pursuant to Section 15-201(a) of the Delaware Revised Uniform Partnership Act, is not an entity distinct from its partners, and brings this action on behalf of itself, the United States pursuant to 31 U.S.C. § 3730(b)(1), REDACTED

12. The Defendant is Quest Diagnostics Incorporated, ("Quest" or "Defendant"), a corporation organized and existing under the laws of Delaware. In numerous filings with the Securities and Exchange Commission ("SEC"), the Defendant describes itself as "the nation's leading provider of diagnostic testing, information and services" serving approximately 50% of the physicians and hospitals in the United States and with over 100 million lives covered by managed care organizations and third-party payers.

13. Quest reported annual net revenues of approximately $6.7 billion in 2007, and had a market capitalization of over $10 billion as of December 31, 2007. Its stock is traded on the New York Stock Exchange under the ticker symbol DGX.

14. The Defendant is the successor to MetPath, Inc., a New York corporation that was organized in 1967. From 1982 to 1996, Defendant was a subsidiary of Corning Incorporated ("Corning") and on December 31, 1996, Defendant became a stand alone business when Corning spun-off its laboratory testing business. In 1999, Defendant acquired SmithKline Beecham Clinical Laboratories and became the nation's largest provider of diagnostic testing. Quest has approximately 43,500 employees, including the largest medical and scientific staff in the laboratory industry, according to its 2007 SEC Form 10-K. It maintains a national network of approximately 2,100 patient service centers, 30-plus service laboratories, 150 "rapid response"

laboratories that annually process over 150 million tests, more than 4,000 professional couriers, and a fleet of 3,000 vehicles and 14 aircraft. Quest has the world's largest database of clinical test results, and employs approximately 900 M.D.s and Ph.Ds. (2007 10-K.)

15. Quest's headquarters is located at 3 Giralda Farms, in Madison, New Jersey, where it is believed to maintain permanent records of its contracts with its clients, including managed care clients, and the work papers and financial analyses that relate to such contracts.

16. In 2003, Quest completed its acquisition of Unilab Corporation, a public company, in a transaction valued at $1.1 billion, solidifying Quest's presence in the State of California. At the time of this acquisition, Unilab was California's leading provider of clinical laboratory services, with about 4,000 employees and annual revenues of $390 million.

17. Based upon the allegations herein, Unilab would have been a named defendant but for its acquisition by Quest. Quest is charged herein with liability for Unilab's alleged FCA violations from late 1999 to 2003, because of Quest's status as Unilab's successor-in-interest, and its ratification and continuation of Unilab's alleged unlawful practices following the Quest acquisition.

V. BACKGROUND AND OVERVIEW

18. The Medicare program, 42 U.S.C. § 1395 et seq., was enacted in 1965 as Title XVIII of the Social Security Act. The Medicare program provides medical insurance for persons age 65 or older and for persons under age 65 who are disabled. The United States Department of Health and Human Services ("HHS"), through the Centers for Medicare and Medicaid Services ("CMS"), (or the Healthcare Financing Administration ("HCFA") prior to 2002), supervises Medicaid and directly administers the Medicare program.

19. CMS issues comprehensive guidelines, including those applicable to clinical laboratory testing. Medicare and Medicaid are the principal government programs that help pay for health care furnished by non-government providers. The Federal annual share of Medicare and Medicaid is approximately $500 billion, one-fifth of the national $2.5 trillion budget (states' Medicaid costs amount to an additional $200 billion).

20. The Medicare program consists of two parts: Part A and Part B.

21. Part A, funded by Social Security taxes, provides major medical insurance coverage for the costs of hospital care, related post-hospital services, home health services and hospice care. See generally 42 U.S.C. §§11395c-395i-4.

22. Part B is a federally subsidized, voluntary health insurance program. It provides supplemental insurance coverage for medical and other services excluded from Part A, including laboratory diagnostic services. See generally 42 U.S.C. §§1395c-1395i-4.

23. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the Federal government and state governments and each sovereign can sue for fraud committed against it and their funding of healthcare programs. The Medicaid program subsidizes the purchase of tens of millions of clinical laboratory tests annually. Although Medicaid is administered on a state-by-state basis, the state programs are required to adhere to Federal guidelines. Federal statutes and regulations restrict the tests and the amounts that the Federal government will pay per test through its funding of state Medicaid programs.

24. Violations of the Medicare and Medicaid health care programs and, in particular the provisions of the Anti-Kickback Statute and the Stark Law, such as here alleged, are each independently actionable under the FCA REDACTED

VI. SUMMARY OF THE INVOLVED CORPORATE ENTITIES

25. The United States headquarters of Corning Glass Works in 1978 was in Corning, New York. In 1982, it owned a majority of the shares of MetPath, Inc. a publicly held clinical laboratory company, which it had acquired in 1981. In 1992, Corning owned 51% of MetWest, Inc., a publicly held clinical laboratory testing company with operations in the Western United States. Thereafter, in 1993, MetWest was reconstituted as a publicly held, clinical laboratory company named Unilab Corporation, ("Unilab") which conducted its business in California. The non-California operations of MetWest were retained by Corning, in exchange for Corning's disposition of its Unilab/MetWest Stock ownership.

26. In 1999, a leveraged buyout of Unilab was completed by Kelso & Company ("Kelso") taking Unilab private. Thereafter, in 2001, Kelso took the company public once again, and then Kelso sold Unilab to Quest, the Defendant, in 2003.

VII. DEFENDANT'S FALSE CLAIMS UNDER MEDICARE AND MEDICAID

(A) Differential Pricing

27. That portion of MetWest which became Unilab in 1993, relied heavily on so-called differential billing, i.e., the use of different sets of fees for the same laboratory services, depending on who the customers were. Beginning in the 1980s, the customers who were being billed the lowest amounts were managed care organizations, including health maintenance organizations (HMOs,) and networks of physicians such as independent practice associations (IPAs), preferred provided organizations (PPOs), and the like.

28. By the 1990s, managed care's capitated segment had grown significantly, particularly in California, and had become Unilab's dominant sector and produced far more specimens than fee-for-service arrangements. Through aggressive negotiations, the managed

care clients had converted their Unilab laboratory contracts into capitated arrangements, whereby Unilab was paid a fixed per-member, per month ("PMPM") amount for all laboratory services, regardless of utilization. Contracts based upon PMPM pricing are commonly referred to as capitated contracts.

29. These capitated arrangements were taking their toll on Unilab, as it bore the full financial risk of laboratory testing utilization. Moreover, these capitated arrangements were being priced lower and lower, ultimately at below cost.

(B) Pull-through Arrangements

30. This Amended Complaint concerns allegations of unlawful, below-cost, discounted capitated prices provided by Quest to managed care companies, including HMOs, IPAs and PPOs, granted to induce referrals of higher-priced Federally reimbursed health care business. Such pricing arrangements constitute illegal kickbacks under the Anti-Kickback Statute. These unlawful discounts were and continue to be provided by Quest to large managed care purchasers of laboratory tests, in exchange for "pull-through" business, that is, the referral of Medicare and Medicaid business by the physicians affiliated with the managed care companies. Pull-through arrangements were the clinical laboratory industry's answer to providing favored below-cost pricing to their managed care clients. To offset their losses resulting from below cost pricing to managed care clients, laboratory companies needed to link the below-cost pricing agreements with managed care clients to higher-priced laboratory testing business, particularly Medicare business, that arose out of the non-managed care practices of the physicians affiliated with the managed care clients. This high-priced "swapped" business would offset the low, commercially unjustifiable prices that the laboratories had provided to managed care clients. By swapping tests at discounted prices for other high-priced tests of non-managed

care patients, the laboratories were positioned to profit from their overall relationships with the managed care clients and their affiliated physicians.

31. A "swap" of discounted pricing on one set of tests in return for the referral of other, more lucratively priced tests reimbursed under Medicare and Medicaid is an illegal kickback under the Anti-Kickback Statute. If the pricing offered by the laboratory to a managed care client is so low that it does not make reasonable commercial sense but for the "pull-through" of other higher-priced Medicare and Medicaid business, the overall pricing and pull-through transaction violates the Anti-Kickback Statute. These violations are, in turn, violations of the FCA. In addition, these same practices constitute violations of the Stark Law prohibiting self-referral by creating prohibited compensation arrangements between the referring physicians, and, directly or indirectly, Quest. These violations are, in turn, violations of the FCA.

32. Under the "swap" arrangement alleged herein, the corporate and regional finance offices of the Defendant would instruct their sales force to persuade managed care clients to influence their affiliated physicians to send lucrative non-managed care laboratory Medicare and Medicaid business to the same Quest laboratory that services the physicians' managed care patients. While not named as defendants herein, the managed care organizations and physicians that are the beneficiaries of the deep-discount/pull-through laboratory pricing scheme are participants in this unlawful arrangement.

33. "Pull-through" arrangements were not common in the first half of the 1980s because physicians were permitted to bill Medicare for clinical laboratory tests performed in their practices, and most physicians' practices included some testing capacity. In 1986, however, Congress changed the rules related to Medicare billing so as to prohibit a doctor from billing Medicare for any laboratory work that he had not personally done himself. Soon

thereafter, California passed the Calderon Act (Business and Professions Code, Section 655.5), which prohibited doctors from marking up laboratory tests that they had not personally performed. Physicians, thereafter, substantially reduced the lab aspect of their practices and, instead, increasingly referred lab tests to outside vendors. Laboratory companies were quick to recognize that this new revenue stream offered an opportunity for them to offset losses on clinical tests performed for managed care patients under capitated payment arrangements.

34. Managed care organizations (IPAs, HMOs, PPOs, etc.) were willing to participate in unlawful pull-through kickback agreements because they wanted deeply discounted, below-cost pricing for the laboratory tests that they had to pay out of their own budgets. That Medicare and Medicaid became liable for much higher prices, patient steering and greater utilization than necessary - the evils that the FCA and State false claims acts were designed to prevent - did not deter either the Defendant's clinical laboratories or their managed care clients in their pursuit of pull-through kickbacks.

(C) Unilab's Rejection of "Pull-through" Arrangements

35. In 1993, Unilab's business model called for as much volume as possible, which meant signing up as many managed care contracts as possible. While this approach increased Unilab's gross revenues, its bottom line suffered, because increasingly costs involved in servicing the managed care capitated contracts exceeded capitated revenues and the pull-through revenues. Moreover, the pull-through strategy presented serious legal issues. Unilab had been advised by its legal advisors that there were potentially serious kickback issues related to the pull-through practices as formulated. As a result, Unilab established a new pricing policy in 1995/1996 that included negotiated increases in the capitated rates under existing contracts with Unilab managed care clients. This decision entailed significant risk as the new pricing policy was a substantial departure from standard industry practice.

36. R. Jeffrey Lanzolatta ("Lanzolatta") joined MetWest in 1990 as vice president and general manager of the Southern California division. He controlled the sales force and became the highest-ranking marketing executive for Unilab's Southern California Division. He was later appointed president of the Southern California Division. As president, Lanzolatta had five sales, marketing and operation managers that reported to him.

37. Lanzolatta agreed to take steps to accomplish the 1995/1996 goal of repricing capitated rates. The Relator has provided to the U.S. Attorney examples of letters sent by Unilab to its customers concerning its demand to increase managed care capitated prices. These letters as well as official reports, such as Unilab's SEC Form 10-K filings and its Annual Reports, were the means by which Unilab announced, and committed itself to, its new pricing structure. Upon management's instructions, in 1996, Unilab's sales and marketing personnel visited virtually every managed care client and delivered letters stating that Unilab was exercising the contract's termination clause and would in 30 days cease providing laboratory services for any managed care client that did not agree to price increases. Unilab based its termination right on a clause that had been inserted into its contracts with clients that allowed for a termination if either party discovered an illegality in their agreement. Unilab's management had in mind recent U.S. Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG") warnings against below-cost/pull-through illegalities when preparing this clause and invoking the termination clause with its managed care clients. Under this policy, Unilab terminated many of its managed care contracts and entered into revised contracts that increased pricing.

38. Unilab's management had hoped that its customers would remain with Unilab, despite the increase in prices, believing they had few other options and that its

competitors would follow its lead to increase managed care pricing. However, Unilab's customers began to slowly slip away to its competitors, who determined to continue the below cost/pull through practice with managed care clients.

39. Moreover, while Lanzolatta had some successes implementing the repricing policy in Southern California, Unilab's Northern California division was uncooperative. The Northern California sales team was headed by Louis Tzoumbas, in San Jose, California, who reported to Ian Brotchie, President of the Northern California Division. The Sacramento general manager, Ralph Monterosa, was also involved in the repricing plan.

40. Unilab had issued $120 million of bonds to fund two large acquisitions and its cash flow was weakening. As the investment community saw Unilab's profitability decrease, Unilab's bond and stock prices nosedived. The decline in both operating profitability and stock market value caused the company's Board of Directors to oust Unilab's CEO, Andrew Baker, in early 1997. At the time of that ouster, Unilab's stock was selling for less than $3 per share. Baker was succeeded as CEO by David Weavil.

(D) Evidence of Unilab's and its Successor Quest's Kickback Practices

41. In 1999 Kelso completed its leveraged buyout of Unilab at a price of $5.85 per share. Lanzolatta, the president of Unilab's Southern California operation, remained in his position following Kelso's buyout in 1999. He stayed in that position following Kelso's subsequent 2001 IPO that took the company public again, and thereafter stayed on after Kelso's sale of Unilab to Quest in 2003. He left the company about a year later.

42. Quest purchased Unilab from Kelso in 2003 for $25 per share compared to the share price of less than $6 when Unilab was sold to Kelso four years earlier.

43. Lanzolatta has stated that following Kelso's acquisition of Unilab, and the installation of a new CEO, Robert Whalen, Unilab returned to the below cost/pull through

strategy. While there had not been significant growth in Unilab's revenues from 1999 to 2003, Lanzolatta attributed the high 2003 purchase price to the fact that during this same time period, Medicare and Medicaid reimbursement had grown considerably, as a consequence of the increased pull-through.

44. Lanzolatta has stated that the pull-through that had significantly increased Unilab's revenues had been the intended consequence of the below-cost PMPM or capitated contracts that Unilab, in the 1999 to 2003 period, had awarded to its managed care clients in return for government insurance and other business.

45. Beginning in 1999 with Kelso's removal of David Weavil and the installation of Robert Whalen as CEO, Unilab had instituted below-cost/pull-through practices that violated the Anti-Kickback Statute, the Stark Law and the FCA,

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46. Upon its 2003 purchase of Unilab, Quest became liable as the successor-in-interest for Unilab's 1999-2003 wrongdoing.

47. During the period that Lanzolatta had remained an executive at Quest, and was in charge of sales and marketing in Southern California, the strategy of below-cost/pull-through kickbacks, that had been emphasized under Kelso and then continued by Quest, had become hugely successful. Lanzolatta is known by the Relator to have stated that Quest's pull-through practice was in full force in California and that it was consistent with Quest's practices nationwide, which was to seek Medicare business as its primary pull-through. According to Lanzolatta and the Relator's investigation, among the major California HMOs that engaged in this scheme with Quest were Pacificare and United Healthcare.

48. Lanzolatta was involved in Unilab's 1999-2003 below-cost/pull- through kickbacks, and thereafter in the similar practices of Quest. He executed the schemes pursuant to his superiors' instructions. The Relator believes that four senior California sales people who worked for Lanzolatta, and knew of and implemented Quest's unlawful kickback practices, were Tod Brett (Tarzana), Mike Hughes (administrator at Tarzana), Beverly Marquez (San Diego) and Kip Vernaglia (Anaheim).

49. The laboratory industry's trade groups and lobbying organizations were aware of, and had, by 1996, become increasingly troubled by the unlawful pull-through practices, as set forth above. When managed care groups were being solicited for business by many of the laboratory companies, the managed care groups sought low prices for laboratory services for their members, usually as a PMPM amount. Many laboratory companies, and Quest in particular, advised their prospective managed care customers that the PMPM levels would be directly affected by the volume of Medicare business that the laboratory company would have referred to it by the group's physicians.

50. The greater the amount of Medicare business that came to a laboratory from referrals by the physicians affiliated with the lab's managed care client (i.e. "pulled through" to the laboratory), the more the laboratory would profit. To induce further referrals, the Defendant would lower the managed care group's PMPM amount. This practice led managed care companies to negotiate aggressively for the lowest possible PMPM from Defendant in exchange for pressuring or requiring their affiliated physicians to refer their more lucrative non-managed care Medicare business to the Quest laboratory with which it had a PMPM agreement. A lab, such as the Defendant, that relied on the pull-through/kickback practice would not give

below-cost pricing to any managed care client with which it did not have an explicit or implicit promise of offsetting, high-priced Medicare referrals.

51. Defendant's below-cost, pull-through pricing model could not succeed but for the pull-through/kickback practices. According to Relator, PMPM business accounted for as much as 45% of the lab specimens tested by Unilab, but only 10% to 15% of Unilab's revenues prior to its acquisition by Quest and these practices continued following Quest's acquisition of Unilab in 2003. Such a disproportionate relationship, the Relator alleges, is proof in itself of Quest's kickbacks.

52. According to Relator, to win business from managed care clients, including HMOs, IPAs, PPOs and the like, the Defendant's pricing had become extraordinarily low and, in fact, below cost. In many cases, prices were approximately 50% of actual cost. Unilab, in the period 1999 to 2003, and Quest, thereafter, could not profit under this pricing model, unless it put into place an unlawful kickback scheme as alleged herein. Payments to Unilab by its managed care clients were as low as $5 for the testing of a specimen. Such amounts were exceeded by Unilab's costs, which included establishment and maintenance of testing centers, pick-ups of the specimens (a fleet of 200 vans, etc.), testing, report writing, report delivery and indirect costs. Since additional tests, under the capitated PMPM agreements, cost the managed care clients nothing extra, many physicians became extravagant in ordering tests. Unilab found that it had to incur substantial additional costs to service those patients, including storefront draw stations, paying rent for sections of doctors' offices, and supporting other "Patient Service Centers." It became impossible for Unilab to survive on $5 of revenue per managed care specimen, according to the Relator. In order for Unilab to satisfy the managed care industry's demand for a PMPM pricing structure and still make a profit, significant pull-

through Medicare revenue would be required in order to reach an adequate blended rate of PMPM and other revenues, notwithstanding serious legal "kickback" concerns that the Defendant knew existed with regard to the PMPM/pull-through strategy.

53. Consequently, it became Unilab's (under Robert Whalen) and Quest's practice to only contract with a managed care client for below-cost tests if the Defendant had done an analysis of the demographics and referral patterns and capacity of the managed care client's physicians and if the Defendant's management had determined that such physicians would refer sufficient Medicare pull-through business to the lab to produce an overall profit. If the Defendant determined that the demographic makeup of a managed care group's physicians was suitable, it then would become the responsibility of the Defendant's laboratory's sales force, managed and pressured by the lab's senior management, and assisted by the managed care entities with which Quest had contracted to provide below-cost capitated contracts to obtain the anticipated lucrative non-managed care business from the affiliated doctors.

54. According to the Relator, the management of the Defendant's managed care clients were told that the steps they took to increase the volume of pull-through revenues to the Defendant would be reflected in their PMPM pricing. The sales forces of the Defendant's clinical laboratories (which were typically not paid commissions on capitated business) lived off the sales commissions they derived from pull-through revenues. The Defendant could not survive on PMPM business that resulted in a net loss. The Defendant's sales managers put pressure on the administrators of its managed care clients to assist in delivering the pull-through business to the lab. Certain physicians who ignored this directive were threatened and, in some cases, dropped from the rolls of the Defendant's managed care plan's roster of physicians. The administrator of a managed care plan knew that, after winning, for example, a 60-cent rather than

a $1.20 PMPM rate from the Defendant, the administrator would be expected to induce his plan's affiliated doctors to refer their lucrative Medicare testing business to the lab.

55. Medicare and Medicaid paid for laboratory services based upon their respective fee schedules. According to the Relator, the average "referred" Medicare/Medicaid reimbursement that had been generated for the Defendant by its pull-through kickbacks was multiples of the amount that the lab received for the same tests performed on managed care members for whom their managed care plan paid only a below-cost PMPM rate. These government insurance payments constituted lucrative, "swap" referral revenues that the OIG's anti-kickback Opinions had long prohibited.

56. The management of the pre-Whalen Unilab had determined that pull-through was not the answer, being particularly sensitive to the OIG's 1993 series of qui tam fraud settlements and the 1994 OIG Advisory Opinion(s) that warned clinical laboratories against entering into this type of kickback arrangement.

57. Significant price increases were implemented by Unilab beginning in 1996. However, after its acquisition of Unilab in 1999, Kelso reversed course and determined to follow a different, far more aggressive, strategy with a different CEO, and replaced Weavil with Kelso's nominee, Robert Whalen. Whalen had been a consultant to Kelso during the bidding process to acquire Unilab.

(E) Analysis of "Kickback" Model of Pricing

58. The Relator has created a capitated managed care revenue and cost model that demonstrates how the Defendant's below-cost PMPM pricing is dependent on kickbacks. This model is based in part upon presentations made by clinical laboratories, including the Defendant, to the UBS Global Healthcare Conference for investors and analysts on February 15, 2005 in New York City. Quest's presentations stated that its revenues increased by 130% over

the five years 2000 to 2005 and made the point, relevant to the Relator's charges, that annual revenue from Medicare and Medicaid was $890 million in 2005, representing 17% of its total revenues. These revenues have increased in the period from 2005 to 2008. The Relator's allegation that a below-cost/pull-through kickback is the engine that largely propelled the Defendant's pricing practices is shown by the conclusions in this analysis that the costs of capitated managed care services exceed related revenues, and that the profitability of the related pull-through business more than makes up for the PMPM losses. Moreover, this analysis concludes that even when considering direct lab costs only (and disregarding indirect costs for analytical purposes), 2005's managed care test costs of the Defendant are approximately $16 per specimen (as compared to its direct costs of $5 to $10 in the mid-1990s), while the Defendant's 2005 revenues from these tests were only $10.17 per specimen. This price/cost discrepancy resulted roughly in a 60% net loss for the Defendant. If the indirect costs that were omitted from this model were factored in, as the OIG opinions require, the Defendant's actual, total percentage loss per specimen would be far greater. The process for determining costs of lab tests is straightforward and well-established. As established by definitive OIG and court anti-kickback opinions, the costs that the OIG requires to be considered in making this analysis include both direct and indirect costs. Quest's Form 10-K for 2004 showed that the company had no difficulty in calculating and reporting both direct and indirect costs, and stated therein that such costs amounted to 58.3% of its net revenues for the year ended December 31, 2004. In the 2007 10-K, Quest conceded that its costs for the capitated tests equaled the costs in these same tests when done for its higher-paying clients.

59. In comparison to the 60% loss, the Defendant's pull-through net profits for the "referred" Medicare and Medicaid tests gave the lab positive margins of 51% and 30%,

respectively. This classic case of kickback "swaps" --an exchange of below-cost discounts for far more lucrative business -- is self-evident.

VIII. UNILAB'S AND QUEST'S KICKBACK SCHEMES

(A) Sale of Unilab to Kelso & Company and Defendant's Implementation of the Illegal Scheme

60. As CEO of Unilab, David Weavil continued his predecessor's policy of imposing higher pricing for managed care clients rather than depending upon the pull through kickback scheme. Slowly, Unilab improved its execution of this policy and its financial results, began to improve. However, concurrent with Weavil's progress, equity markets had heated up and as a result Unilab's board was informed by its financial advisors that its stock (which had been as low as 37 cents per share but had climbed to $2.00), could be sold at an attractive price. Twelve bidders competed for the acquisition of Unilab, and Kelso & Company ("Kelso") was the winning bidder at $5.85 per share. Kelso acquired 83.7% of Unilab's common shares in November 1999, and the remainder in early 2000. The entire Unilab Board, and most of its senior corporate management, left the company soon after Kelso completed the acquisition and installed Robert Whalen ("Whalen"), as CEO.

61. Once Unilab completed its acquisition, Unilab became a privately held company. Thereafter, under the aegis of Kelso executives and its new CEO, Whalen, an unlawful pull- through strategy was implemented. Whalen was a senior executive at National Health Labs ("NHL") when it paid a $110 million qui tam fine. The president of NHL was sent to jail. When Whalen assumed control of Unilab, he told its executives that the prior CEOs' repricing strategy was a mistake, that it caused the company to lose market share, and that the company needed to operate in the way that the rest of the industry was doing business, namely, (i) engage in bidding wars for managed care business, (ii) accept below-cost capitated contracts

with managed care companies and (iii) implement a pull-through strategy that depended upon kickback referrals of Medicare and Medicaid tests to stimulate Unilab profits.

62. Managers who were later replaced by Whelan warned him about the below- cost pull-through pricing issue. Following the 1994 OIG Advisory Opinion, the same warnings were repeated in a November 1999 OIG Advisory Opinion concerning "swaps". This topic was included as a part of an anti-kickback discussion in an initial briefing session with Whalen in December 1999, which occurred immediately after Kelso's completion of the Unilab acquisition. The OIG's 1999 Advisory Opinion warned laboratory companies against engaging in the very practices that Whalen was espousing. Similar warnings were also given to David Gee, the incoming general counsel. Ironically, while in private practice, Gee had written extensively for publicly circulated laboratory newsletters, specifically referring to the OIG opinions and warning the industry about the dangers of below-cost/pull-through kickbacks. The same issue was also raised with a senior Kelso executive and attorney, Michael Goldberg, while the Unilab sale to Kelso was pending. Goldberg had previously been a senior partner with the New York law firm of Skadden, Arps, Slate, Meagher and Flom before joining Kelso.

63. Whalen became the main architect of Unilab's reliance on below-cost/pull-through kickback arrangements. This approach was continued and accelerated after Quest acquired Unilab. According to the Relator, the Kelso and Unilab representatives stated that they believed that it was time to make a killing on the business. Whalen owned 944,469 shares of Unilab; Michael Goldberg and David Wahrhaftig were officers of Kelso, which owned 13,842,741 Unilab shares. Goldberg and Wahrhaftig were directors of Unilab and Lanzolatta and David Gee were officers of Unilab. Each owned 12,329 stock options of Unilab, according

to Quest's 2002 Proxy Statement. These executives and directors insisted that Unilab change its course and adopt the below- cost/pull-through strategies that were prevalent in the industry.

64. During the next few years under Kelso and Whalen, Unilab's implementation of its illegal below-cost/pull-through strategy helped the company flourish and lead the California laboratory business sector. Unilab went public again in 2001 at an offering price of $14 per share. Kelso retained the stock that it had previously purchased from Unilab shareholders for $5.85. In 2003, Kelso sold these shares as part of Unilab's sale to Quest for $25 per share. Quest brought in its own managers. Lanzolatta received a severance agreement after working for about one year for Quest and helping it to administer its kickback strategies, which paralleled Unilab's. According to the Relator, Quest has continued to follow its unlawful pull-through business strategy, not only in California, but nationwide.

(B) How Unilab And Then Quest Implemented Their Kickback Strategy

65. Starting in the mid-1990s, a new health insurance paradigm rapidly became prevalent (starting in California and soon spreading across the country): managed care. Very quickly the majority of business available to lab companies from insurance groups was capitated business, in which the HMO demanded a low fixed price for the provision of all the lab testing performed on its members. In 1998, 92.7% of HMOs in the Los Angeles Metropolitan Statistical Area paid their primary care physicians on a capitated basis. P. Kongstoedt, *Essentials of Managed Care*, p. 106 (4th Ed. 2003). This fixed payment, expressed as a "per member, per month" (PMPM) amount, became the standard in the industry. Soon, labs realized that market forces were pushing their PMPM pricing so low that the only way they could make money was to obtain the lucrative Medicare business from the HMO's participating physicians. Therefore, labs devised a scheme to attract Medicare business by offering below-cost PMPM pricing in exchange for the efforts of HMOs to require or coerce their participating physicians to

send their Medicare tests to that lab. By 2002 as patients grew to dislike the lack of choice available under true managed care capitated plans and enrolled physicians and other providers (including clinical laboratories) resisted accepting capitation risk, the market slowly began shifting to a hybrid approach, known as "point of service" ("POS") plans, which offered patients somewhat greater choice and compensated physicians and other providers on a discounted fee-for-service basis. Nonetheless, in 2008, there continue to be a substantial number of HMOs that have capitated arrangements with their participating physicians and clinical laboratories, wherein the latter continue to employ below-cost discounts to obtain the Medicare pull-through.

66. According to the Relator, Unilab (under Whalen) and Quest, as its successor, would analyze the number of physicians affiliated with a particular managed care group, the specialties of these physicians, and how much Medicare and Medicaid laboratory work the physicians could be induced to refer to Unilab or Quest through the use of below-cost pricing provided to the physicians' managed care groups. This analysis was crucial to the laboratory's offer of a fixed PMPM rate to a particular group: the laboratory would estimate the revenue that would be derived from the group's pull-through business and then establish a PMPM rate that would guarantee the laboratory its desired "swap" profit.

67. In the mid-1990s, Rob O'Brien, then a high-ranking executive of U.S. Healthcare (which has since been purchased by, and folded into, Aetna), told Quest, "you know, you need us, even if you need to give us below-cost pricing as low as 50 cents per member, per month for our capitated business, because otherwise, you won't be able to get a foot into the door to get access to our valuable Medicare lab business." Agreements were entered into between Unilab (acquired by Quest) and HMOs, wherein the PMPM was, in fact, as low as $.50. Unilab's CFO estimated the cost of each test specimen at $5 to $10 in the mid-1990s. In that

same time period, Quest's Senior and National Sales Vice President, Bob Peters, urged that Quest obtain as clients as many HMOs as possible, because through them Quest could cause the participating physicians to send Quest their pull-through Medicare lab business. Peters stated, "I will never understand how a sales representative with Quest can be anything but successful once we have all the major plans in our pocket, and all the reps have to do is go and get the pull-through." By "pull-through," Peters was referring to the HMO plans' Medicare lab business, which he often referred to as the "good stuff", and not to the HMO's other programs, such as POS plans. Peters was still making these same comments recently.

68. Quest found that the various competing laboratories fought to obtain the capitated business, regardless of how low the labs' below-cost pricing had to go, because the capitated work was necessary to get a foot in the door of the physicians' offices to seek their Medicare lab business. Throughout the 1990s and as late as 2004, capitated business far exceeded the fledging POS business (which was marginally profitable), making the capitated business the essential access point to the valuable Medicare business. Through numerous conversations with insurance companies such as Aetna and Cigna (by far the two largest HMO providers under contract with Quest), Quest executives made sure that each knew of Quest's interest in obtaining the physicians' Medicare business, and that the below-cost pricing quoted for the capitated business was dependent on Quest's success in obtaining the Medicare business. Absent that success, Quest would not, and could not, have maintained the below-cost pricing model for capitated business.

69. Once Quest gained access to an HMO's physicians, it had an enormous advantage over the labs with which it competed. Quest and other clinical laboratories regarded

as axiomatic that physicians who were in the routine of sending their capitated tests to a particular lab would also send their Medicare tests to that lab.

70. Quest's goal was to become the laboratory of choice for HMOs such as Aetna with below-cost capitated pricing, and then – with the full knowledge, approval and assistance of the HMO – induce the physicians who treated the HMO's patients to refer Medicare business to Quest. Quest and its abettors, the HMOs and the HMO physicians, orchestrated and effectuated unlawful referrals by the physicians of lucrative Medicare tests: Top-level Quest executives continually demanded that Quest's sales force induce HMO physicians to refer Medicare business to Quest, and prevailed upon HMOs to make clear to their network physicians that Quest's below-cost pricing was only sustainable in return for the physicians' referral of Medicare lab work to Quest and to secure those referrals through the use of physician bonuses and threats of exclusion.

71. Quest executives actively and directly participated in the Quest-Aetna and Quest-Cigna "anti-leakage initiatives," and prepared monthly spread-sheet reports tracking the lab-ordering activities of the managed care physicians. In meetings at an Aetna office in Manhattan, at 99 Park Avenue, the Quest managed care team and sales managers sat down with Aetna representatives, including their medical directors, to go through the list of the biggest leakers of "capitated" business in order to plan ways to gain all the Aetna work and the related Medicare pull-through business for Quest. The term "leakage" generally means lab tests that Quest has agreed to provide at below-cost capitated pricing to an HMO that the HMO's participating physicians, for whatever reason, send to another lab. Quest's sales management was adamant that if a physician was not sending his capitated work to Quest, he would have to

be made to do so as a first step toward obtaining the referral of his Medicare work – this was the lynch pin of Quest's kickback scheme.

72. The term "pull-through" has a specific meaning throughout the lab industry: the referral of Medicare business. Quest's sales force would visit Aetna participating physicians to attempt to convince them to send all of their capitated work and most significantly their associated Medicare business to Quest. Quest executives also worked directly and jointly with Aetna medical directors to put pressure on physicians who were not sending enough of their capitated tests to Quest.

73. Medicare business was so attractive to labs in general, and Quest in particular, even though Medicare reimbursement was not as high as some commercial fee-for-service plans, because it was the "ultimate pull through." It could be sent to any lab, in the physicians' discretion. Medicare reimburses for its lab tests more quickly than any other payor, typically within two weeks. Moreover, Medicare is billed electronically, with no paperwork involved. Medicare's methods for coding and payment, such as assigning standard ICD-9 codes and CPT codes, meant that physicians would know which codes to bill and relatively few claims were disputed. When Medicare disputed a claim, it promptly notified the laboratory of the reasons for the dispute and afforded the laboratory the opportunity to rebill the claim. In addition to reducing billing costs, electronic billing lowered the risk of errors in bills sent to Medicare. Furthermore, Medicare typically represents higher specimen volumes than other payors, because older patients tend to make more doctor visits and to require more lab tests.

74. To the extent that the HMO physicians ordered Medicare tests from Quest, the HMO would be allowed to continue to benefit from Quest's "remuneration," its below-cost

capitation rates for laboratory services, and the physicians, who were key players in assuring Quest's successful acquisition of Medicare tests, would participate in Quest's favored pricing.

75. According to Relator, throughout the period covered by this Amended Complaint, Quest tracked the volume and value of each physician's referrals of Medicare, Medicaid and commercial fee-for-service patients' tests, as well as the physician's below-cost, capitated tests. Quest compiled this information in variously formatted reports and reviewed them on a monthly basis. These reports used demographic practice assumptions that allowed Quest to infer the volume and value of profitable Medicare tests sent by each physician to laboratories other than Quest.

76. If Quest determined that there was significant leakage in the physician's capitated test referrals, Quest would, in the first instance, contact the physician directly. The HMOs, through their executive staffs, including their medical directors, directly assisted Quest's efforts to obtain Medicare referrals from the physicians. The HMOs knew that without their assistance, Quest's remuneration to them would be revised downward or eliminated. Thus, if, on an individual basis, Quest was unable to persuade an unprofitable physician to decrease his referral leakage, Quest would complain to such physician's HMO management. Quest would tell the HMO management that it would not be able to maintain the level of below-cost pricing for its capitated tests unless the HMO's enrolled physicians referred more pull-through Medicare tests, which often began with a reduction of their referral leakage. This information would be relayed by the HMO to the physicians, who knew that if Quest were to increase its pricing to the HMO, the HMO's profitability would be reduced, and the physicians' compensation would, in turn, be reduced through reductions in bonuses paid to the physicians by the HMO. If the threat of decreased compensation was insufficient to change the physicians' referral practices, the

HMO would apply pressure by threatening such physicians with removal from the HMO's physician panels. Quest engaged in such initiatives with both Aetna and Cigna, among other managed care organizations that were Quest clients.

77. Scott Orzolek was the member of Quest's managed care management team who was most focused on obtaining Medicare pull-throughs. His mantra was, "Follow the Medicare. If we are not getting the capitated HMO crap [i.e., if there is leakage], we are certainly not getting the Medicare pull-through. We need to button down these accounts that are leaking. We need to take whatever steps are necessary to insure that these accounts do not leak. Aetna and Cigna have volunteered their medical directors to help pressure these leaking accounts." Orzolek would review each sales manager's report monthly, account by account, to identify those accounts on which Quest was not getting enough Medicare referrals. Each utilization report would show the amount of Medicare business from the specific accounts. Accounts that were not sending enough Medicare tests were identified as target accounts, and were tracked on a monthly basis, including by means of the Top 2500 Aetna and Cigna Reports that surveyed the physician offices' with the largest number of monthly lab tests.

78. The Top 2500 reports included: (i) the total number of requisitions by doctor account in a recent month and the averages covering a six-month period; (ii) the breakout for the most recent month of the number of requisitions by payor, including, notably, Medicare; and (iii) a "comments" column, which is most informative.

79. The Comments column included notes that monthly meetings with doctors or their offices had been conducted together with the outcomes of such meetings, and indicated when an "Aetna letter" had been sent to a physician. So-called Aetna letters were sent by Aetna at the behest of Quest and sought to pressure Aetna's physicians to make pull-through referrals

to Quest. The Top 2500 Report documents Quest's efforts to convince doctors to send their pull-through work to it and clearly tracks the number of Medicare referrals from each doctor's office. For example, the average percentage of Medicare referrals in Manhattan is about 20% of total referrals, slightly below the national average of about 25%. By viewing the number of Medicare referrals received from a particular doctor as a percentage of total referrals from that doctor, the Quest sales representative could determine whether the doctor was sending Quest its expected amount of Medicare work, taking into consideration the nature of the doctor's practice. When a doctor fell short of Quest's expectation, the sales representative was instructed to pressure the doctor to send more Medicare referrals to Quest.

80. In June 2006, Quest introduced a new "Payor Mix Report," which has been used to the present time in conjunction with the Top 2500 Report, to identify accounts which show capitated leakage and lower than anticipated Medicare pull-through. The Payor Mix Report is the successor to two less sophisticated reports known as "Variance Reports" and "Accounts by Insurer Reports." Scott Orzolek, Eastern District Director of Sales, described the Payor Mix Report to sales managers as "your bible," and "the best selling tool we've ever had."

81. The Payor Mix Report generally parallels the format of the Top 2500 Report, except that, for each physician account, the Payor Mix Report records, on a monthly and cumulative basis, the revenues received by Quest from each HMO in which the physician participated, from each fee-for-service insurer and from Medicare for all tests referred by the physician. In a simple application, the Report allows Quest sales personnel to assess whether Quest is receiving the appropriate dollar volume of Medicare referrals simply by multiplying the pertinent Medicare demographic percentage (20% in New York) by the total revenues recorded for all other payers on the Report.

(C) Renumeration to Physicians

82. Quest's below-cost capitated pricing to physician groups and networks and to HMOs that, in turn, contract with such physician-owned entities results in the payment of "remuneration" to the referring physicians under the Anti-Kickback Statute and the Stark Law.

83. Quest has two basic forms of contractual arrangements with managed care organizations. First, Quest contracts directly with physician groups and a variety of networks composed of physicians, most often, so-called preferred provider organizations (PPOs) and independent practice associations (IPAs), without the contractual intervention of a health maintenance organization. The OIG has taken the position that for purposes of identifying the recipient of the remuneration, physicians "stand in the shoes" of their groups and networks. 42 CFR §411.354(c)(ii). Therefore, when Quest contracts directly with physician groups and networks, their constituent physicians receive remuneration directly from Quest in the form of below-cost capitated pricing.

84. Secondly, Quest contracts with health maintenance organizations (HMOs) which, in turn, contract with physician groups and networks. In such arrangements, the HMOs use performance or risk allocation provisions (principally, bonuses) in their contracts with physician groups and networks to pass along the economic benefits and burdens associated with Quest's below-cost capitated pricing to the physicians who refer tests to Quest.

85. HMOs are compensated on a capitated basis. As here relevant, HMOs contract with the primary care physicians and certain specialists in their networks on the same basis, that is, a per member per month prepayment (PMPM). To induce their participating physicians to refer their laboratory tests to Quest (with which the HMOs also had a capitated arrangement) instead of another laboratory to which Quest would be required to pay an out-of-network fee, the HMOs created so-called bonus pools. In addition to the PMPM paid monthly to

an HMO's referring physicians, separate amounts are added by the HMO to various risk/bonus pools held by it. The physicians do not initially receive the money in these pools. Rather, the money is held by the HMO and expenses incurred by the HMO for out-of-network testing will be deducted from the bonus pool. Any surplus in a bonus pool is shared with or paid to the HMO's physicians.

86. The bonus pools were used by the HMOs, in conjunction with Quest, to reduce leakage and secure for Quest the Medicare pull through from the HMOs' physicians. The physicians were remunerated through the bonuses, and benefited directly from the below-cost capitated pricing that Quest afforded in consideration of the pull through.

87. HMO bonuses played an important role in inducing participating physicians to refer their Medicare business to Quest. Doctors were acutely aware of the HMOs' bonus structures. Physicians were urged by the HMO's to send their Medicare tests to Quest, and they knew their bonus payments would be reduced by leakage. The physicians fully understood that the amount of pull-through business that they sent to Quest would enable Quest to offer even lower capitated pricing to the HMO, which meant, in turn, that the HMO could pay bonuses to its physicians. Aetna and other HMOs, had established monthly ($1,000 to $1,500) or yearly bonuses based on how efficient physicians were in curtailing capitated leakage to other labs of tests covered by Quest's capitated pricing to Aetna. Such practices, orchestrated and run by Aetna, made clear to the physicians the close connection between Aetna and Quest, and Aetna's desire that Quest get all of the physicians' lab business. Quest's expectation, and the reason it paid its "remuneration" to managed care, was that Medicare referrals would follow from the referrals of the below-cost capitation lab tests, and this expectation was rewarded: Quest's Medicare revenue grew by hundreds of millions of dollars.

88. Bonus arrangements for physicians were instituted by Aetna to further the joint Quest-Aetna goal to induce the physicians' referrals of Medicare lab tests to Quest. The physicians found these bonus programs to be highly desirable, and sought their rewards avidly. The bonuses for which the physicians were made eligible by Aetna, were adjusted downward dollar-for-dollar by the "out-of-network" charges paid by Quest to other labs as a result of the physician's capitated "leakage."

89. This bonus was an essential mechanism for eliminating leakage. The bonuses caused the physicians' financial incentives to be directly aligned with Quest's and Aetna's. The leakage of tests by a physician not only increased Aetna's costs (through the payment of out-of-network fees) and reduced Quest's revenues (based on its experience that Medicare referrals followed capitated referrals), but also decreased the physician's income (as out-of-network fees reduced the bonus otherwise payable to such physician).

IX. SEC FILINGS CORROBORATE THE RELATOR'S ALLEGATIONS

90. As companies having securities registered under the Securities Act of 1993 and the Securities Exchange Act of 1934, Unilab and Quest are required to file quarterly and annual reports with the Securities and Exchange Commission. Information contained in these filings strongly corroborates the existence of the unlawful below-cost/pull-through kickback scheme alleged by Relator.

(A) Quest SEC Reports

91. Quest has reported in its Form 10-K for 1997 that, as far back as the mid-1990s (prior to its entry into the California market), its business model was to employ a national and regional process to identify prospective customers.

92. Quest also acknowledged in its 1997 10-K that the referral of tests by physicians for their patients who were not affiliated with managed care was Quest's principal source of business. (1997 Form 10-K at p. 5). Quest's SEC filings corroborate that it was engaged in below-cost/pull-through kickback policies across the country long before it added California to its portfolio of false claims. In its 1997 Form 10-K, Quest warned that as the number of patients covered under managed care plans continued to increase, there would be less fee-for-service business "to offset the low margin (*and often unprofitable*) managed care business." (*Id.* at p. 7) (emphasis supplied). Quest further warned that since physicians were increasingly affiliated with more than one managed care entity, and therefore may be required to refer to different labs depending on the coverage of their patients, labs might not receive any fee-for-service referrals from such physicians. (*Id.*) This dynamic is what made Medicare, as far as Quest was concerned, the preferred insurance. Quest also stated that the significant shift away from traditional fee-for-service health care to managed healthcare had an adverse effect and

caused the decline in profitability, when volume shifted to lower-priced managed care business. (*Id.* at p. 31.)

93. Quest's 1997 Form 10-K (at p. 6) presented its volume and revenues, highlighting, among its other revenues and costs, its managed care capitated business. On its face, this schedule shows that managed care-capitated contracts were grossly under priced, starting at least as early as 1997 and prior to the time that Quest expanded its fraudulent activities to California:

Category	Volume of Business	Revenue Per Specimen
Managed care-capitated	15% to 20%	$5 to $15
Patients	5% to 10%	$60 to $80
Medicare	20% to 25%	$20 to $30
Monthly	35% to 40%	$15 to $35
Third party, fee-for-service	15% to 20%	$30 to $40

94. Quest's Form 10-K for 1999 (page 11), reflects a similar disparity. Managed care-capitated business is reported as 20% - 25% of the total volume of business, but produced only 5 to 10% of the company's revenue.

95. Quest further stated (at p. 5) in its 1999 Form 10-K that "managed care organizations typically agree to discourage their affiliated physicians from sending tests to out-of-network laboratory providers", and (at p.9) that "[p]hysicians requiring testing for patients who are not covered by a capitated managed care contract are one of the primary sources of Quest Diagnostics' clinical laboratory business."

96. Quest has admitted its knowledge of the Anti-Kickback Statute as it pertained to its laboratory business. In its 1999 Form 10-K Quest acknowledged (at p. 23) that

"[i]n November 1999, the OIG issued an advisory opinion concluding that the industry practice of discounting client bills may constitute a kickback if the discounted price is below a laboratory's overall cost (including overhead) and below the amounts reimbursed by Medicare." Quest acknowledged in its Form 10-K for 2000 (at p. 18) that the "five-year corporate integrity agreement with the OIG" that it signed in October 1996 included taking steps to "adopt pricing guidelines," a promise that the Relator alleges has been totally disregarded. Its admitted liability under prior *qui tam* lawsuits also documents Quest's multi-faceted previous frauds and its knowledge of FCA prohibitions.

97. In its 10-K for 2003 (p. 8), Quest stated that if it cannot agree on pricing with the managed care organization, then Quest becomes non-participating and can bill only the physician or patient, not the managed care organization. This leads to loss of business, Quest reported, because physicians will refer their other tests to a participating provider whose testing is covered by patient's managed care benefit plan. This mimics the blueprint of Quest's anti-kickback scheme: Quest's motive has been to obtain the capitated business, even at below-cost, in order to obtain the physicians' Medicare and Medicaid tests.

98. Quest confirmed in its 2003 Form 10-K (at p. 15) its continued belief that "our other business [e.g. fee-for-service] *may significantly depend on continued participation in Medicare and Medicaid* programs, because many customers want a single laboratory to perform all of their clinical laboratory testing services, regardless of whether reimbursements are ultimately made by themselves, Medicare, Medicaid or other payers." (Emphasis added.) This is further confirmation of an element of Quest's scheme: the importance of securing the referral or "pull though" of Medicare business from the physicians, with the help of their HMOs or organizations. Pursuant to Quest's anti-kickback scheme here alleged, the key to obtaining the

Medicare tests was to be the provider of the capitated tests, regardless of the loss those tests caused to Quest.

99. In addition, Quest stated in its 2004 Form 10-K (at p. 7) that healthcare insurers, capitated and fee-for-service, combined, represented approximately one-half of testing volume and one-half of total net revenues. Based upon the data disclosed in its 2004 Form 10-K, these one-half proportions could only have been accomplished through the development of "blended" rates, that is, averaging below-cost capitated rates with higher rates charged to other payers:

Category	Volume of Business	Revenue Per Category
Managed care-capitated	15% to 20%	5% to 10%
Patients	2% to 5%	5% to 10%
Medicare/Medicaid	15% to 20%	15% to 20%
Monthly	30% to 35%	20% to 25%
Healthcare fee-for-service	30% to 35%	40% to 45%

100. Quest's 2004 Form 10-K also addressed the issue of laboratory "costs", which are a key element of the OIG Advisory Opinions that concern whether a kickback has occurred. Quest recognized that costs are essentially the same under capitated contracts as they are under other arrangements, while noting that, as the Relator has alleged, the lower-than-average revenues from capitated arrangements make them less profitable: "In 2004, we derived approximately 19% of our testing volume and 7% of our net revenues from capitated payment arrangements." (2004 Form 10-K at p. 36) This disparity between volume and revenue percentages corroborates that Quest's below-cost capitated arrangements were the inducement for Medicare "pull through" business. Quest also reported in its 10-K, with respect to costs, that

"[t]he diagnostic testing industry is labor intensive. Employee compensation and benefits constitute approximately one-half of our total costs and expenses. Cost of services consists principally of costs for obtaining, transporting and testing specimens. Selling, general and administrative expenses consist principally of the costs associated with our sales and marketing efforts, billing operations (including bad debt expense), and general management and administrative support" (p. 36) and that the "[c]ost of services . . . was 58.3% of net revenues for the year ended December 31, 2004." (p. 41)

101. Quest's 2007 S.E.C. Form 10-K provided the background to the ongoing kickback scheme of the prior decade: "[W]e continue to participate in such programs [Medicare and Medicaid] because we believe that our other business [e.g. fee for service] may depend, in part on continued participation in these programs, because certain customers may want a single laboratory capable of performing all of their clinical laboratory testing services, regardless of who pays for such services." 2007 Form 10-K at p. 14. Quest further stated in its 2007 Form 10-K (at p. 7) that its managed care contracts nationwide were priced aggressively and that the laboratory expected to capture through these contracts additional payments from referrals by physicians for their non-managed care patients. Quest's 10-K also referred (at p. 42) to the use of penalties to be assessed by insurance companies against its physicians who did not comply with the insurance company's demands for lab test referrals. From other sources, the Relator can show that Aetna, for one, paid bonuses to its physicians to consummate Quest's kickback scheme.

(B) Unilab SEC Reports

102. Unilab's 1997 Form 10-K made clear its commitment to revise its managed care pricing upward (until Whalen arrived and changed the company's approach; as represented in its Form 10-K for 2001): "Increasingly, Unilab, like other major laboratory

companies, has come to recognize that the pricing received in relation to the cost of services provided to managed care patients was disproportionately low, and the Company undertook a concerted effort in 1997 to improve the situation. To this end, Unilab renegotiated contracts representing approximately two-thirds of its covered lives and received an avenge price increase in excess of 50% of those renegotiated contracts."

103. Unilab's business goal, soon to be reversed by Whalen, was to increase its "at risk" capitation rates. The Company noted that in 1998, its major managed care contracts had a 50% increase in capitation rates, and in 1997 over 70% of these contracts were repriced an average of 50% higher. The two CEOs who had preceded Whalen had taken seriously the rejection of the below-cost kickback strategy.

104. The 2000 10-K reported that, "California has the highest enrollment rate - - approximately 40% of the population - - in managed care plans of any state . . . It was also viewed as a competitive advantage in obtaining additional non-managed care business generated from many of the same offices which were serving managed care patients . . . we came to recognize that the pricing received in relation to the cost of services provided to managed care patients was disproportionately low, and we undertook a concerted effort in 1997 to improve the situation".

105. In its Form 10-K for 2000 Unilab reported that: (i) California accounted for 14% of the national market for laboratory diagnostic services and that, (ii) starting in 1996, the company renegotiated and increased its pricing for services provided to managed care clients, and (iii) managed care-capitated contracts account for 35% to 40% of the business volume, but produce only 10% to 15% of the Company's revenues.

106. Whalen's implementation of a kickback policy is corroborated in Unilab's Form 10-K for 2001. The Unilab of 2000, the first full year under Whalen's management, executed policies far different from its 1996-1999 rejection of below-cost pricing. The company's emphasis on a policy that stressed a major repricing of managed care contracts disappeared. The excuse given was that contracts could not be repriced, because "due to the financial condition of managed-care groups, repricing was negligible."

X. OTHER EXHIBITS THAT SUPPORT THE RELATOR'S ALLEGATIONS

(A) Letters to Clients

107. As early as 1996, Unilab began notifying its managed care clients of the need for price increases to assure compliance with the Anti-Kickback Statute. This is shown by a September 16, 1996 letter sent by Unilab's Chairman and CEO, Andrew Baker, to Dr. Berezovsky, Chairman and CEO, AHI Healthcare Systems, Inc., and by a December 30, 1996 letter from Unilab's Southern California Division President, Jeffrey Lanzolatta, to Mr. Jack Bunkley, American Health, Inc. In these letters, Unilab advised its managed care clients that the capitated payment structures then in place were not sustainable and that more realistic fee levels would need to be developed. Absent such restructuring, the clients were advised that Unilab would terminate their agreements after a 30-day notice. These letters are representative of the letters widely distributed to Unilab's managed care client base.

(B) Unilab's Industry-Wide Notice

108. Unilab widely reported its pricing revisions -- its explicit rejection of kickback strategies - and provided notice to the industry, in general, and its customers, in particular, of the need for a change in its pricing practice. The February, 2000 edition of First Monday, the "Laboratory Industry Report Monthly Market Monitor," had the headline

"UNILAB HIKES PRICES IN CA". The article reported, "California's largest independent lab, Unilab Corp. (Tarzana), is aggressively raising prices on capitated contracts for lab services, according to court documents and filings with the Securities & Exchange Commission. . . Unilab demanded lab capitated rates of $1.10 per-member per-month for commercial HMO members. . .. [O]nly three months earlier, Catholic Healthcare West (CHW) had signed a three-year contract. . . for rates of $0.40 PMPM. . . . Meanwhile, documents recently filed with the SEC indicate that Unilab is aggressively raising rates for other capitated contracts. For the first six months of 1999, the company repriced contracts representing 460,000 capitated lives at an avenge price hike of approximately 50%."

(C) **Draft Letter to Customers**

109. A draft Unilab letter that was intended for its customers after the OIG's 1999 Advisory Opinion No. 99-13 specifically addressed the discounting of laboratory testing. The letter set forth the applicable law, namely, "any discount that falls below a laboratory's average cost to perform the testing (which the OIG defines as the total of all costs including labor, overhead, equipment, etc., divided by the total number of laboratory tests) is a possible violation of the Federal Anti-Kickback law and the Medicare Anti-Discrimination law." Accordingly, it was the company's intention to alert Unilab's customers of the need to review and, where necessary, revise "all of its customer pricing." Despite the adjustments that would be necessary, Unilab envisioned continuing its business relationships by meeting "any competitor's price that is legal under the OIG Advisory Opinion." This letter is substantial evidence that Unilab and its successor Quest were well aware of the Medicare rules applicable to them, and of the steps that needed to be taken in order not to violate the kickback laws.

(D) Relevant Publications By Unilab's General Counsel

110. David W. Gee, Esq. authored an article in the January, 1999 "G-2 Compliance Report." His views at that time concerning kickbacks in Federal health care clinical laboratory programs are relevant because this article was published shortly before he left his private law practice and became Unilab's general counsel. Gee's article was critical of government efforts to define compliance standards in terms of "fair market value." In presenting his position, he used the "cost" of laboratory tests as the type of standard that should be used, rather than "fair market value." He recognized the value of a "concrete and workable 'below cost' threshold" of illegality because it lent "itself both to compliance and to enforceability because the 'below cost' threshold is one that can be determined and honored by each individual lab without reference to the conduct or motives of others in the marketplace." His article also endorsed the same "but for" standard that was used by the OIG in its 1999 Advisory Opinion (No. 99-2), namely, "But for the physician's Medicare (or other federal) lab work, does this discount make business sense?".

111. Gee followed his January, 1999 article with another article in the March 1999 edition of G-2 Compliance Report that discussed the OIG's Advisory Opinion No. 99-2, issued on February 26, 1999. He described the Opinion as an anti-kickback prohibition on offering discounts for one segment of business in order to induce the referrals of other Federal healthcare program business. Moreover, he explicitly connected this Opinion to the practice of clinical laboratories such as the Defendant's, and noted that the criterion used by the OIG for determining whether a kickback occurred was not "fair market value" but whether or not the discount was "'commercially reasonable in the absence of other, non-discounted business.' This is in essence a 'but for' test: 'But for the Medicare (or other Federal work), does a particular discount make business sense'." In his conclusion, Gee specifically warned companies doing

Federal health care program business to "[b]eware of ... pricing below average (not marginal) cost." Gee took this knowledge with him when he began advising Unilab on its pricing for clinical lab services.

XI. FEDERAL ANTI-KICKBACK LAW VIOLATED BY DEFENDANT

112. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under Medicare and Medicaid, as well as other Federal programs. A violation of the Anti-Kickback statute is actionable under the FCA.

(A) Applicable OIG Opinions

113. OIG Advisory Opinion No. 99-2, issued February 26, 1999, clearly sets forth the OIG's view that the capitated-payment practices of the Defendant here at issue result in prohibited remuneration under the Anti-Kickback Statute. As noted in their Opinion, the anti-kickback statute has been interpreted by controlling court decisions to cover any arrangement where *one* purpose of the remuneration is to obtain money for the referral of services or to induce further referrals. Moreover, as stated in OIG Opinion No. 99-2, "[P]rice reductions create a risk that a supplier may be offering remuneration in the form of discounts on business for which the purchaser pays the supplier, in exchange for the opportunity [provided to the supplier] to service and bill for higher paying Federal health care program business reimbursed directly by the program to the supplier. In such circumstances, neither Medicare nor Medicaid benefits from the discount; to the contrary, Medicare and Medicaid may, in effect, subsidize the other payer's discounted rates." As further stated in the foregoing OIG Opinion, "[i]n evaluating whether an improper nexus exists between a discount and referrals of Federal business in a particular arrangement, we look for indicia that the discount is not commercially reasonable in the absence of other non-discounted business. . . .[D]iscounts... that are particularly suspect include . . .

discounted prices that are below the supplier's cost . . . the above pricing arrangement [] independently gives rise to an inference that the supplier and the [managed care company] may be swapping discounts on [certain] business in exchange for profitable non-discounted . . . business, from which the supplier can recoup losses incurred on the discounted business, potentially through over utilization or abusive billing practices." In a footnote to the foregoing, OIG stated, "[W]e do not think it sufficient to consider only a supplier's marginal costs. Rather, in determining whether a discount is below cost, we look, for example, at the total of all costs divided by the total number of [tests]" (*Id.*)

114. OIG Opinion No. 99-13, issued November 30, 1999, applied the concepts of OIG Opinion No. 99-2, to below-cost charges for pathology services, stating: "In 1994, we issued a Special Fraud Alert describing certain laboratory practices that implicated the anti-kickback statute. The Special Fraud Alert set forth our analysis that when a laboratory offers or gives to a referral source anything of value for less than fair market value, an inference may be made that the thing of value is offered to induce the referral of business." Special Fraud Alert, October 1994, was an opinion that applied the Anti-Kickback Statute to "Arrangements for the Provision of Clinical Lab Services" of a similar nature to those of the Defendant.

115. OIG Opinion No. 04-16, issued November 18, 2004, followed the holdings of the previously cited OIG opinions, that "[t]he OIG's position on the provision of free or below-market goods or services to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the anti-kickback Statute depending on the circumstances. For example . . . when a laboratory offers or gives an item or service for free or less than fair market value to a referral source, an inference arises that the item or service is offered to induce the referral of business." Furthermore, "[b]oth parties have obvious motives

for agreeing to swap nonmonetary 'discounts' on composite rate business for referrals of noncomposite rate business: [the managed care company] to maximize expense recoupment under the composite rate system and the Lab to secure lucrative business in a highly competitive market."

116. In short, the Inspector General's Office has made it clear in its Advisory Opinions that the practice here at issue violates the Anti-Kickback statute. Moreover, defendant has acknowledged in its SEC filings its awareness of the Anti Kickback Statute and of the OIG's stated position that the "swapping" of discounted capitated business for the referral of more profitable Medicare business violates the Anti-Kickback Statute.

(B) Department of Health and Human Services letters

117. Discount arrangements for clinical laboratories such as the Defendant's were addressed in an April 26, 2000, HHS guidance letter, which reiterated the other cited directives, holding that "[a]n anti-kickback statute violation. . . arises if the discount whatever its size is implicitly or explicitly tied to referrals of Federal business."

118. In its guidance letter entitled "Discount Arrangements, Clinical Laboratories and SNFs", dated September 22, 1999, HHS made clear that its directives apply to "pricing schemes (such as capitation arrangements) made in conjunction with explicit or implicit agreement to refer other facility business."

(C) Knowledge of Defendant

119. The Anti-Kickback Statute provides that it is illegal to "knowingly and willfully" offer or pay any remuneration (including any kickback) directly or indirectly, overtly or covertly, in cash or in kind, to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment maybe made, in whole or in part, under a Federal health care program.

120. The overwhelming majority of Federal circuits have construed this "knowingly and willfully" requirement to mean that specific knowledge of the Anti- Kickback Statute is not required.

121. In any event, Unilab and Quest had "knowledge" of the Anti-Kickback Statute, as indicated by their (1) admissions in their own Forms 10-K, concerning the applicability of kickback laws to their practices, (2) the opinions of their outside and inside counsel, of which the companies became aware before proceeding with their fraudulent conduct, and (3) the Defendant's previous payments of large False Claims Act fines.

(D) Kickbacks as a Predicate for False Claims Act Liability

122. Compliance with the Anti-Kickback Statute is "central to the reimbursement plan of Medicare" and is a prerequisite to receiving or retaining payments from Medicare or Medicaid. The Defendant laboratory, in filing claims for reimbursement by Medicare and/or Medicaid, has certified, either expressly or impliedly through its participation in a Federal health care program, its compliance with the Anti-Kickback Statute. False Claims Act liability exists as a matter of law, when a claim is submitted for payment (whether paid or not) and it has been shown that a knowing violation of the Anti-Kickback Statute has occurred. In sum, either pursuant to provider agreements or claims forms, or in another appropriate manner, the Defendant's participation in various Federal health care programs require it to certify truthfully that it has complied with applicable Federal rules and regulations, including the Anti-Kickback Statute. Quest's claims to Medicare and Medicaid were made by electronic submissions which included certifications of compliance with Federal reimbursement rules and the Anti-Kickback Statute.

123. Actions brought under the FCA may be predicated on violations of the Anti-Kickback Statute. If a Defendant engages in conduct that violates the Anti-Kickback

Statute, and causes the government to pay a claim which it would not have paid had the government been aware of the violation, then the FCA is violated.

124. Each element of a statutory Anti-Kickback violation under Section 1320a-7b(b)(2)(B) is presented in this Amended Complaint, namely: (i) Quest knowingly and willfully (ii) paid remuneration to physicians affiliated with HMOs and/or IPAs and PPOs (iii) to induce such physicians (iv) to purchase or order lab tests from Quest for which payment was made under Medicare and Medicaid.

125. Unlawful "remuneration" is the below-cost capitated payments that Quest offered the HMOs (Aetna, Cigna, UnitedHealthcare, et al.), for laboratory tests performed on their members, irrespective of the number or cost of the tests actually ordered. These below-cost arrangements are not commercially reasonable in the absence of the "pull through" Medicare business as described herein. During the relevant time period the below-cost, per member, per month amounts paid to Quest were considerably lower than Quest's annual average costs of processing a typical HMO patient's yearly lab tests.

126. If one purpose of the remuneration is to gain Federal healthcare business, the Anti-Kickback Statute is violated, which, in turn, is the basis for an FCA violation. Here, the profitable commercial purpose sought was the referral to Quest by the HMO's participating physicians of their Medicare and Medicaid business. Quest provided below-cost capitated pricing in order to gain such business.

127. As has been shown, referring physicians were remunerated directly by Quest and indirectly by Quest using HMOs as contractual intermediaries to induce test referrals. However, the Anti-Kickback Statute can be violated without a finding that the referring physicians received remuneration of any sort.

128. Section 1320a-7b(b)(2) of the Anti-Kickback Statute is violated by an entity, including a clinical laboratory, that

> [K]knowingly and willfully . . . pays any remuneration . . . directly or indirectly . . . to any person [including an HMO] to induce such person —
>
> (B) to . . . *arrange for or recommend* purchasing. . . or ordering any . . . service or item [including a lab test] for which payment is made in whole or in part under a Federal health care program. (emphasis added).

129. Each element of a statutory violation under Section 1320a-7b(b)(2)(B) is present in the case at hand and is supported by ample evidence, namely: (i) Quest knowingly and willfully (ii) paid remuneration to HMOs (iii) to induce such HMOs (iv) to arrange for or recommend (or indeed, to require or coerce) such HMOs' physicians (v) to purchase or order lab tests from Quest for which payment was made under Medicare and Medicaid.

XII. STARK LAW VIOLATED BY DEFENDANT

130. The referral to Quest of laboratory tests reimbursed under Medicare by physicians affiliated with managed care organizations, which, in turn, receive below market pricing from Quest, violates the Stark Law. In consequence, each and every bill submitted by Quest for a Medicare-reimbursable test referred by such physicians constitutes a false claim under the FCA.

131. The Defendant laboratory, in filing claims for reimbursement by Medicare has certified, either expressly or impliedly through its participation in a Federal health care program, its compliance with the Stark Law. FCA liability exists as a matter of law, when a claim is submitted for payment (whether paid or not) in violation of the Stark Law. Quest's claims to Medicare were made by electronic submissions which included certifications of

compliance with the Stark Law. Quest's false certification of compliance with the Stark Law is a violation of the FCA.

132. The basic prohibition under Subsection (a)(1) of the Stark Law is as follows:

> (a) Prohibition of certain referrals
>
> (1) In general
>
> . . . [I]f a physician . . . has a financial relationship with [a laboratory], then
>
> (A) the physician may not make a referral to [the laboratory] for the furnishing of designated health services [e.g., laboratory tests] for which payment maybe made under [Medicare], and
>
> (B) [the laboratory] may not present or cause to be presented a claim [to Medicare] . . . .
>
> 42 U.S. C. §1395nn(a)(1)

133. Therefore, when a "financial relationship" exists between a physician and a laboratory, the Stark Law flatly bans both the referral of Medicare-reimbursable tests to the laboratory and the laboratory's billing of Medicare for such tests, regardless of the intention of the parties. The Stark Law is a strict liability statute.

134. "Financial relationship" is defined in Subsection (a)(2) of the Stark Law as an "ownership or investment interest" in the laboratory or a "compensation arrangement" between it and the referring physician. "Compensation arrangement" is defined in Subsection (h)(1) as "any arrangement involving any remuneration between a physician . . . and a [laboratory, including] any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." The Stark Law's concept of "remuneration" includes any type of remuneration whatsoever, and coincides with the concept of "remuneration" under the Anti-Kickback Statute.

135. The regulations interpreting the Stark Law can be found at 42CFR Parts 411 and 424. Remuneration is defined to include "any payment or other benefit." 42 CFR §411.351.[1] Given the broad sweep of this definition, Quest's low-cost or below-cost pricing to HMOs and other managed care organizations resulted in the payment of remuneration to the physicians who referred Medicare-reimbursable tests to Quest.[2]

136. The Regulations under the Stark Law distinguish between a "direct compensation arrangement," i.e., where "the remuneration passes between the referring physician . . . and [a laboratory] without any intervening persons or entities," and an "indirect compensation arrangement." (42 CFR § 411.354(c)) An indirect compensation arrangement exists under § 411.354(c)(2) if: (i) "between the referring physician . . . and [the laboratory] there exists an unbroken chain of any number . . . of persons or entities that have financial relationships . . . between them (that is, each link in the chain has . . . a compensation arrangement with the preceding link)", (ii) "the referring physician . . . receives compensation . . . that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician to [the laboratory]" and (iii) the laboratory "has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician . . . receives [such remuneration or compensation]." CMS takes the position that the

1 The so-called Phase III Regulations (42 CFR Parts 411 and 424) under the Stark Law were adopted by CMS effective December 4, 2007. The Phase III Regulations generally superseded both the so-called Phase II Regulations published on March 26, 2004 (69 Fed. Reg. 16054) and the so-called Phase I Regulations published on January 4, 2001 (66 Fed. Reg. 865). Nevertheless, the Phase I and Phase II Regulations offer important insight into CMS's interpretation of the Stark Law and, together with the Phase III Regulations, are "intended to be read together as a unified whole." Phase III preamble at 4.

2 Although there are a number of statutory exceptions to the basic prohibition against compensation arrangements under the Stark Law, none of them is applicable under the facts of this action. In understanding the rationale for the exceptions, it is worthwhile to note that they generally impose a fair market value requirement, which could not be satisfied by Quest's deeply discounted, below-cost pricing.

"knowledge" element set forth in clause (iii) is "the same as in the False Claims Act." Phase II at 14.

137. CMS has illustrated the unbroken chain of financial relationships with the following example (Phase I at 17; accord, Phase II at 12):

> For example, if a referring physician owns an interest in a hospital . . . and the hospital contracts for services with a clinical laboratory to which the physician refers, there would exist a chain of persons or entities having financial relationships between the referring physician and [the clinical laboratory].

138. Phase II at 12, goes farther:

> If, however, the contracted laboratory charges were less than fair market value, the arrangement could qualify as [a prohibited] indirect compensation arrangement between the referring physician and the clinical laboratory, provided the laboratory knew of, or had reason to suspect, the referring physician's ownerships interest in the hospital. (Emphasis added.)[3]

139. In commenting on the types of compensation arrangements that take into account the volume or value of referrals CMS stated (Phase I at 31):

> Physician compensation arrangements that were fixed in amount but conditioned either expressly or implicitly on the physicians referring patients to a particular provider or supplier took into account the value or volume of referrals under the statute.

140. The facts put forth by the Relator satisfy each of the elements of a Stark Law violation, based either on a direct or an indirect compensation arrangement between Quest and its referring physicians. It is indisputable that when a physician orders a test from Quest, that physician has made a "referral" to Quest within the meaning of the Stark Law. It is also clear that the provision by Quest of clinical laboratory tests at less than fair market value constitutes remuneration to the physician who orders the tests, regardless of whether Quest has a

3 CMS has thus taken the position that below-market pricing of laboratory tests is such a benefit as constitutes "remuneration" in the context of an indirect compensation arrangement.

contract directly with such physician or his physician organization or with some intervening entity

141. When Quest has a contract directly with a referring physician's "physician organization" (including conventional group practices or larger physician networks, such as IPAs and PPOs) in which the physician has an ownership interest,[4] there is deemed to be a direct compensation arrangement between the referring physician and Quest. If the physician orders a Medicare test from Quest, the Stark Law is violated; nothing more is required to be shown.

142. When there is a chain of contracts among Quest, one or more intervening entities and a physician who orders Medicare tests from Quest, there is deemed to be an indirect compensation arrangement between the referring physician and Quest. The Stark Law is violated when the physician orders a test.

143. Here, each element of an indirect compensation arrangement is present. First, there is an "unbroken chain" of compensation arrangements between Quest and an intervening entity (such as an HMO), between that entity and another (such as an IPA) and between the latter and a physician who orders tests from Quest. The remuneration paid by Quest in the form of below-market test pricing passes through each entity successively and ultimately benefits the referring physician.

144. Secondly, the referring physician receives remuneration that varies with, or takes into account, the volume or value of referrals between the physician and Quest. Quest's discount pricing would vary based on the volume and value of the pull-through referrals. Similarly, physician bonuses are directly affected by non-Quest referrals. This satisfies the

4 Physicians with ownership interests in physician organizations are said to "stand in the shoes" of such organizations. Phase III, 42 CFR 411, §354(c)(1)(ii).

second element. Moreover, Quest's fixed discounts were conditioned expressly or implicitly on the physicians' referral of tests, i.e., the discount takes into account the referral of the tests.

145. The third element, namely, Quest's "knowledge" of the referring physician's compensation, is plainly satisfied. While "reckless disregard" or "deliberate ignorance" is sufficient, Relator has presented evidence that Quest had actual knowledge of the fact that referring physicians received non-market value remuneration and that their compensation took into account the value and volume of referrals. This economic consequence was essential to the execution of Quest's pull-through scheme.

146. Clearly, Quest violated the Stark Law. The below-market and below-cost pricing constituted "remuneration" and thereby created a "compensation arrangement" between Quest and the managed care physicians who received the same. In turn, those physicians referred tests to Quest that were reimbursable under Medicare and Quest, in fact, billed Medicare for those tests.

XIII. DAMAGES

147. As set forth above, Defendants knowingly submitted or caused to be submitted to Medicare and Medicaid reimbursement claims that were based upon violations of the Federal REDACTED nti-Kickback Statute and the Stark Law, for the period 1996 to the present, in violation of 31 U.S.C. § 3729, causing damages to the United States' Medicare and Medicaid programs. The Relator estimates that Quest's illegal Medicare kickbacks over the period 1996 through 2008 resulted in the Federal REDACTED governments paying in excess of one billion dollars pursuant to false claims prohibited by the FCA, which constitute actual damages, without regard to fines or penalties.

XIV. FIRST CAUSE OF ACTION

False Claims Act: Presentation of False Claims and Making and Using a False Statement or Record (31 U.S.C. § 3729 (a)(1) and (a)(2)).

148. Plaintiff repeats and re-alleges each allegation in paragraphs 1 through 147 of this Amended Complaint, as though fully set forth herein.

149. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 et seq., as amended.

150. By virtue of the acts described above, Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States. Government for payment or approval by Medicare and Medicaid.

151. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false and/or fraudulent records and statements, to induce the Government's Medicare and Medicaid programs to approve and pay such false and fraudulent claims.

152. By virtue of the act described acts above, Defendant has falsely certified its compliance with the Anti-Kickback Statute and the Stark Law in connection with the submission of Medicare and/or Medicaid reimbursement forms from at least January 1, 1996 to the present.

153. Each claim submitted by and each reimbursement received by Defendant that was as a result of an unlawful kickback scheme and/or as a result of items or services ordered by physicians who have improper financial relationships with Defendant represents a false or fraudulent record or statement and/or a false or fraudulent claim for payment.

154. The Relator cannot at this time identify all of the false claims for payment that were caused by Defendant's conduct. The false claims were presented by hundreds of

separate entities, across the United States REDACTED from the period at least from 1996 to present. Relator has no control over or dealings with such entities and has no access to the records in their possession.

155. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendant, paid and continues to pay the claims that would not be paid but for the Defendant's illegal kickback scheme and inducements and illegal compensation arrangements under the Stark Law.

156. By virtue of the false or fraudulent claims made by Defendant, the United States has suffered and has been damaged, and continues to be damaged, in substantial amounts to be determined at trial. The Medicare and Medicaid programs have paid many tens of thousands of claims, amounting to many hundreds of million of dollars, for illegal reimbursements that were obtained by the Defendant, from 1996 to present, and, therefore, is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,000 to $11,000 for each violation.

XV. SECOND CAUSE OF ACTION

False Claims Act: Conspiracy to Submit False Claims (31 U.S.C. § 3729 (a)(3))

157. Plaintiff repeats and re-alleges each allegation in paragraphs 1 though 147 of this Amended Complaint, as though fully set forth herein.

158. This is a claim for false damages and penalties under the False Claims Act, 31 U.S.C. § 3729 et seq., as amended.

159. By virtue of the act described above, Defendant conspired with others, including without limitation, physicians and managed care organizations to defraud the United States by creating an illegal kickback scheme in violation of the Anti-Kickback Statute and by

creating prohibited financial relationships between Defendant and its co-conspirators in violation of the Stark Law. Defendant took substantial steps in furtherance of the conspiracies by, *inter alia*, agreeing to "swap" discounted capitated prices in exchange for referrals of higher-priced Federally reimbursed heath care business, including Medicare and Medicaid.

160. The Government, unaware of the Defendant's conspiracy, paid and continues to pay claims that would not be paid absent the unlawful conspiracy.

161. By virtue of Defendant's conspiracy and the acts taken in furtherance thereof, the United States has been damaged and continues to be damaged in substantial amounts to be determined at trial. The Medicare and Medicaid programs have paid many tens of thousands of claims, amounting to many hundreds of million of dollars, for illegal reimbursements that were obtained by the Defendant, from 1996 to present, and, therefore, is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,000 to $11,000 for each violation.

PAGES 57-80, WHICH INCLUDE PARAGRAPHS 162-329, HAVE BEEN REDACTED IN THEIR ENTIRETY

PRAYER

WHEREFORE, Realtor/Plaintiff prays for judgment against the Defendant as follows:

(a) that Defendant cease and desist from violating 31 U.S.C. § 3729 *et seq.*

REDACTED

(b) that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of U.S.C. §3729;

REDACTED

PAGES 82-84, WHICH INCLUDE PARAGRAPHS (g) – (w) OF THE PRAYER FOR RELIEF, HAVE BEEN REDACTED IN THEIR ENTIRETY

REDACTED

(bb) that Plaintiff/Relator be awarded the maximum amount allowed pursuant to 3730(d) of the False Claims Act,

REDACTED

(cc) that Plaintiff/Relator be awarded all costs and expense of this action, including attorneys' fees and expenses; and

(dd) that Plaintiff/Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial as to all issues triable by a jury.

Dated: New York, New York
December 1, 2008

Respectfully submitted,

TROUTMAN SANDERS LLP

By: _____

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DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial as to all issues triable by a jury.

Dated: New York, New York
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AS TO THE REDACTED AMENDED COMPLAINT

Dated: New York, New York
November 18, 2009

Respectfully submitted,

MICHAEL LAW GROUP

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